

117TH CONGRESS  
1ST SESSION

# H. R. 1905

To amend the Federal Food, Drug, and Cosmetic Act to allow the sponsor of a drug to use a non-animal test as an alternative to an animal test for purposes of demonstrating the safety and effectiveness of a drug if such approach satisfies the requirements of the applicable statutes and regulations.

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## IN THE HOUSE OF REPRESENTATIVES

MARCH 16, 2021

Mr. BRENDAN F. BOYLE of Pennsylvania (for himself, Ms. DEAN, Mr. FITZPATRICK, and Mr. HASTINGS) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to allow the sponsor of a drug to use a non-animal test as an alternative to an animal test for purposes of demonstrating the safety and effectiveness of a drug if such approach satisfies the requirements of the applicable statutes and regulations.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Alternatives to Ani-  
3 mals for Regulatory Fairness Act of 2021” or the “AARF  
4 Act of 2021”.

5 **SEC. 2. FINDINGS.**

6 The Congress finds that—

7 (1) the Food and Drug Administration (in this  
8 section referred to as the “FDA”) often requires  
9 pharmaceutical companies to conduct or commission  
10 testing on dogs and other animals to assess the safe-  
11 ty or effectiveness of new drugs, even though such  
12 testing is inefficient, expensive, and ineffective;

13 (2) the National Institutes of Health states,  
14 “Approximately 30 percent of promising medications  
15 have failed in human clinical trials because they are  
16 found to be toxic despite promising preclinical stud-  
17 ies in animal models. About 60 percent of candidate  
18 drugs fail due to lack of efficacy”;

19 (3) current FDA nonbinding pharmaceutical  
20 testing guidelines support the use of alternatives to  
21 animal testing to improve the effectiveness and effi-  
22 ciency of drug development;

23 (4) current FDA drug testing guidance for the  
24 pharmaceutical industry states, “consideration  
25 should be given to use of new in vitro alternative  
26 methods for safety evaluation”;

1                         (5) the FDA’s drug testing guidance for industry additionally states, “alternative approaches . . . can also be used . . . . The use of any of these approaches can reduce overall animal use in drug development”;

6                         (6) the FDA writes that alternatives to animal testing, “may help bring FDA-regulated products to market faster, with improved efficacy, or prevent products with increased toxicological risk from reaching the market. Also critical is the potential for these advances to replace, reduce, and/or refine animal testing”;

13                         (7) pharmaceutical companies are reducing animal testing by investing in the development and use of alternative methods, which studies show are often more effective and efficient than traditional animal use;

18                         (8) the FDA states, “FDA encourages sponsors to consult with us if they wish to use a non-animal testing method they believe is suitable, adequate, validated, and feasible”; and

22                         (9) in some cases, drug manufacturers and sponsors have not been allowed by the FDA to use alternatives to animal testing to fulfill regulatory re-

1        requirements, despite the FDA's support for this tech-  
2        nology in its industry guidance document.

3 **SEC. 3. ALTERNATIVES TO ANIMAL TESTS.**

4        Section 505 of the Federal Food, Drug and Cosmetic  
5        Act (21 U.S.C. 355) is amended by adding at the end the  
6        following new subsection:

7        "(z) ALTERNATIVES TO ANIMAL TESTS.—The Sec-  
8        retary shall allow the sponsor of a drug to use a non-ani-  
9        mal test as an alternative to an animal test for purposes  
10      of demonstrating the safety and effectiveness of a drug  
11      under this section if such approach satisfies the require-  
12      ments of the applicable statutes and regulations.".

